

**REMARKS**

Claims 1-30 are pending in the application, claims 1, 11, 12 and 22 are withdrawn from consideration and claims 2, 6, 18 and 21 have been amended. Support for the claim amendments may be found throughout the specification, including the claims as originally filed. In particular, support for the amendments to claims 2, 6 and 18 can be found, for example, at page 33, lines 31-33, at page 110, lines 16-18, page 112, lines 5-18, and in Example XX at pages 129-134, etc. No new matter has been added.

Amendment of claims should in no way be construed as an acquiescence to any of the Examiner's rejections. The amendments to the claims are being made solely to expedite prosecution of the present application and do not, and are not intended to, narrow the claims in any way. Applicants reserve the option to further prosecute the same or similar claims in the instant or in a subsequent patent application.

**Rejection of claims 2-7, 9, 13, 23, 25, 27, and 29 under 35 U.S.C. § 102(b)**

Claims 2-7, 9, 13, 23, 25, 27, and 29 were rejected under 35 U.S.C. § 102(b) as being anticipated by Pujol et al., Proc. Amer. Assn. Of Cancer Res. Ann. Meeting 35: 165 (1994). The Action states that: "the claims recite a p63 protein [ ] which can encompass the p63 protein taught by Pujol et al." and that "[t]here are no limitation[s] found in the claims that would preclude the p63 protein taught by Pujol et al." (Office Action at 2).

The rejection is respectfully traversed.

Applicants respectfully disagree with the rejection, however, in an effort to expedite prosecution of the application the claims have been amended. The claim amendments are believed to obviate the rejection. In particular, as stated in the Response and Amendment filed on May 20, 2003, the Pujol et al. sequence (Accession No. X69910) shows only 5-8% homology with the sequences set forth in SEQ ID NOs: 13-24. Accordingly, Pujol et al. does not anticipate the claims of the instant application. In view thereof, reconsideration and withdrawal of the rejection of claims under 35 U.S.C. § 102(b) is respectfully requested.

**Rejection of claims 2-7, 9, 13, 16, 18-19, 23, 25, 27, and 29 under 35 U.S.C. § 103(a)**

Claims 2-7, 9, 13, 16, 18-19, 23, 25, 27, and 29 were rejected under 35 U.S.C. §103(a) as being unpatentable over Pujol et al. for reasons of record. Applicants' respectfully disagree with the rejection, however, in an effort to expedite prosecution of the application the claims have been amended. The claim amendments are believed to obviate the rejection. Since the sequence of Pujol et al. shows only 5-8% homology with the sequences of the instant application, the methods as presently claimed in the instant application would not have been obvious over the teachings of Pujol et al. In view thereof, reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. § 103(a) is respectfully requested.

**Rejection of claims 24, 26, 28, and 30 under 35 U.S.C § 112, first paragraph**

Claims 24, 26, 28, and 30 were rejected under 35 U.S.C. § 112, first paragraph, for reasons of written description. The Action states that:

“The claims recite an “amino acid sequence at least 98% identical” to SEQ ID Nos: 13-24 as part of the invention. However, there does not appear to be an adequate written description in the specification as-filed of the essential structural feature, physical/chemical properties, know[n] characteristics, or correlative function that provides for proper identification of SEQ ID NOs 13-24.” (Office Action at 3-4)

and

“Applicant does not appear to have reduced to practice any amino acid sequence which is 98% identical to any one of SEQ ID Nos: 13-24. Neither has Applicant provided a sufficient written description of any structure that may be correlated with the desired function of SEQ ID Nos.: 13-24. Thus the genus of compounds encompassed by this term is extensive and the artisan would not be able to recognize that the Applicant was in possession of the invention as now claimed.” (Office Action at 4)

The rejection is respectfully traversed.

Applicants respectfully submit that the specification is replete with teachings that show Applicants were in possession of the invention at the time of filing the application. In particular, as stated in the Office Action, the Written Description guidelines make clear that “the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice ... sufficient to show the

applicant was in possession of the genus" (Office Action at 4). Applicants actually reduced to practice and disclosed in the application 12 different protein sequences that fall within the genus of p63 proteins. In particular, the specification discloses 6 different isoforms of p63 (e.g., TA<sub>p</sub>63 $\alpha$ , TA<sub>p</sub>63 $\beta$ , TA<sub>p</sub>63 $\gamma$ ,  $\Delta$ N<sub>p</sub>63 $\alpha$ ,  $\Delta$ N<sub>p</sub>63 $\beta$  and  $\Delta$ N<sub>p</sub>63 $\gamma$ ) from 2 different species (e.g., mouse and human). Indeed, the specification teaches an inter-species family of related genes which are also each part of an intra-species family (See e.g., specification at page 20, lines 20-22). In addition to the multiplicity of species that were actually reduced to practice, Applicants further provided teachings about the structure and/or physical properties of the proteins in the genus. For example, the specification discloses that the p63 proteins may be generally represented by the formula X-Y-Z, wherein X represents the N-termini of the proteins, e.g., a  $\Delta$ N, a TA\*, or TA polypeptide sequence, Y represents the core domain of the protein, and Z represents the C termini, e.g., the  $\alpha$ ,  $\beta$ , or  $\gamma$  polypeptide sequences (see e.g., specification at page 18, line 25 to page 19, line 15). Additionally, Figure 2 of the application provides a schematic of the human p63 domain structure for the major isotypes of p63. Based on the teachings in the specification showing the features and common elements of a variety of p63 proteins, one of skill in the art would be able to identify regions of a p63 sequence which would be amenable to substitutions and/or modifications.

Furthermore, contrary to the Examiner's statement, Applicants have reduced to practice and provided multiple examples of sequences which are 98% identical to any one of SEQ ID NOS: 13-24. In fact, comparison of SEQ ID NOS: 13-24 *via* Clustal alignment (provided in the Response filed on May 20, 2003) indicates that the sequences provided in the specification show a range of identities from 69-99% between the various sequences of SEQ ID NOS: 13-24. Accordingly, the species provided in the specification provide support for a genus which is much broader than 98% identity with any one of SEQ ID NOS: 13-24 since the specification provides support for species showing only 69% identity between sequences. For example, SEQ ID NO: 21 has 83% identity with SEQ ID NOS: 13 and 14, 96% identity with SEQ ID NOS: 15 and 24, 69% identity with SEQ ID NOS: 16 and 22, 72% identity with SEQ ID NOS: 17 and 23, 93% identity with SEQ ID NO: 18, and 91% identity with SEQ ID NOS: 19 and 20. SEQ ID NO: 19 shows 98% identity with SEQ ID NO: 13, 97% identity with SEQ ID NOS: 14 and 22, 91% identity with SEQ ID NOS: 15 and 21, 96% identity with SEQ ID NO: 16, 94% identity with SEQ ID NO: 17, 88% identity with SEQ ID NO: 18, 99% identity with SEQ ID NO: 20, 95%

identity with SEQ ID NO: 23, and 87% identity with SEQ ID NO: 24, etc. Therefore, for each of SEQ ID NOs: 13-24 there are multiple examples of p63 proteins which support the genus having 98% identity to any one of SEQ ID NOs: 13-24. Accordingly, Applicants have actually reduced to practice a representative number of species which more than adequately cover the scope of the genus as currently claimed.

Accordingly, the subject matter of claims 24, 26, 28, and 30 was clearly described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Therefore, reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. § 112, first paragraph, is respectfully requested.

**CONCLUSION**

Based on the above Remarks, it is respectfully submitted that this application is in condition for allowance. Accordingly, allowance is requested. If a telephone conversation with Applicant's Agent would expedite prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 832-1000.

Respectfully submitted,

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